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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,384	08/29/2008	Ajit Lalvani	HO-P03388US0	7392
26271	7590	05/12/2011		
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			EXAMINER SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			05/12/2011	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nstacey@fulbright.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/593,384	LALVANI, AJIT	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28February2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-13 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-13, 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28February2011 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1645

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 28 February 2011, is acknowledged. Claims 2, 3, 4, 5, , 6, 7, 8, 9, 12, 13, 15, 16, 17 and 21 have been amended. Claim 1 has been cancelled.
2. Claims 2-13 and 15-23 are pending and under consideration.

### **Rejections Moot or Withdrawn**

3. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for differentiating between known and unknown regions, is moot in light of the cancellation of the claim.
4. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for sequences "shown in", is moot in light of the cancellation of the claim.
5. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Agger et al (WO01/79274, 25 October 2001), is moot in light of the cancellation of the claim.
6. The objection to Figure 1A is withdrawn in light of the replacement Figure 1A.
7. The objection to Figure 3 is withdrawn in light of the specification amendment.
8. The rejection of claims 2-13 and 15-20 under 35 U.S.C. 112, second paragraph, as being indefinite for sequences "shown in", is withdrawn in light of the claim amendments.
9. The rejection of claims 8-13, 15 and 16 under 35 U.S.C. 102(b) as being anticipated by Agger et al (WO01/79274, 25 October 2001), is withdrawn in light of the claim cancellations and amendments.
10. The rejection of claims 17-20 under 35 U.S.C. 103(a) as being unpatentable over Aggers et al ((WO01/79274, 25 October 2001), is withdrawn in light of the claim amendments.

### **Rejections Maintained**

Art Unit: 1645

11. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for peptides "represented by" SEQ ID Nos:2 to 18, is maintained as the amendment does not correct the indefiniteness.

12. The rejection of claims 2-13 and 15-20 under 35 U.S.C. 112, second paragraph, as being indefinite for differentiating between known and unknown regions, is maintained for reasons of record.

Applicants argue that the claim amendments obviate the rejection.

The examiner has considered applicants' argument, in light of the claim amendments, but does not find it persuasive.

The peptide in claim 2, (i)(a) remains a peptide "having the sequence of SEQ ID NO:1" which permits any number of amino acids on either end of the known region.

The peptide in claim 6 remains a peptide "having the sequence of at least 8 consecutive amino acids of the sequence shown in SEQ ID NO:1", which permits any number of amino acids on either end of the known region.

13. The rejection of claims 21 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

As newly amended, the claims are now drawn to a method of ascertaining the stage of an *M. tuberculosis* infection in a human comprising determining whether there is a differential T cell response to different *M. tuberculosis* antigens in the human.

While the amendment now restricts the source of antigens to *M. tuberculosis*, the scope of claimed inventions states that any antigen isolated from *M. tuberculosis* will obtain the desired results, i.e., staging of infection.

Art Unit: 1645

The instant specification only utilizes four *M. tuberculosis* antigens, Rv3879c, Rv1989c, Rv3873 and Rv3878. The specification does not show that all antigens isolated from *M. tuberculosis* can fulfill the scope of the claims. Thus, the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

### **New Rejections Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 depends from newly amended claim 21 which now restricts the antigen source to *M. tuberculosis*.

Claim 23 is the method of claim 21 wherein T cell responses to one or more of Rv3879c, ESAT-6, Rv3878, Rv1989c are measured. It is unclear, in light of the new amendment to claim 21 if the antigens of claim 23 are the same as the antigens of utilized in claim 21, or are in addition to the antigens utilized in claim 21.

If they are the same, it is also unclear how the method is performed with one antigen of the "one or more" given that claim 21 utilizes "antigens", denoting more than one antigen is to be utilized in order to obtain a "differential T cell response".

### **Conclusion**

Art Unit: 1645

15. All claims are finally rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1645

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P Swartz/

Primary Examiner, Art Unit 1645

May 9, 2011